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17025," IBR approved for \$170.520(b) and 170.524(a).

(4) ISO/IEC 17025:2017(E)—General requirements for the competence of testing and calibration laboratories (Third Edition), 2017–11, "ISO/IEC 17025," IBR approved for §§ 170.520(b), and 170.524(a).

(5) ISO/IEC 17065:2012(E)—Conformity assessment—Requirements for bodies certifying products, processes and services (First Edition), 2012, "ISO/IEC 17065," IBR approved for §§170.503 and 170.523(a).

[81 FR 72471, Oct. 19, 2016, as amended at 85 FR 25955, May 1, 2020]

# PART 171—INFORMATION BLOCKING

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AUTHORITY: 42 U.S.C. 300jj-52; 5 U.S.C. 552.

SOURCE: 85 FR 25955, May 1, 2020, unless otherwise noted.

# Subpart A—General Provisions

#### §171.100 Statutory basis and purpose.

(a) *Basis.* This part implements section 3022 of the Public Health Service Act, 42 U.S.C. 300jj-52.

(b) *Purpose*. The purpose of this part is to establish exceptions for reasonable and necessary activities that do not constitute information blocking as defined by section 3022(a)(1) of the Public Health Service Act, 42 U.S.C. 300jj– 52.

#### §171.101 Applicability.

(a) This part applies to health care providers, health IT developers of certified health IT, health information exchanges, and health information networks, as those terms are defined in §171.102.

(b) Health care providers, health IT developers of certified health IT, health information exchanges, and health information networks must comply with this part on and after November 2, 2020.

#### §171.102 Definitions.

For purposes of this part: